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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,482	04/25/2001	Gary B. Gordon	10980523-1	9824

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IP Administration
Legal Department, 20BN
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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 03/19/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/842,482

Applicant(s)

Gordon et al

Examiner

Maurie G. Baker

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 31, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit 1639.

1. The Response filed December 31, 2002 (Paper No. 6) is acknowledged. Claims 33-35 were amended, and no claims were added or cancelled. Therefore, claims 33-35 are pending and under examination.

Status of Objections and Rejections

2. The previous claim objections and also claim rejections under the second paragraph of 35 U.S.C. 112 are withdrawn in view of the claim amendments. The rejection under 35 U.S.C. 102 is maintained. However, the rejection has been slightly rewritten in view of the claim amendments. Also, a new rejection under the second paragraph of 35 U.S.C. 112 necessitated by amendment is set forth below.

New Rejections (necessitated by amendment) ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

The claim lacks clear antecedent basis for “an oligonucleotide” in step (a) as the previous reference in the claim is to “oligonucleotides” (emphasis added).

Maintained Rejections (changes necessitated by amendment)
Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Cozzette et al (US 5,200,051).

The following analysis is used for this rejection:

Claim 33 is directed to a “method of fabricating a plurality of individual chips for conducting chemical reactions”. The claim goes on to recite in step (a) “each site for electronically carrying out a chemical reaction”. Similarly, claim 34 is directed to a “method of fabricating a plurality of individual chips for conducting a part of a synthesis of oligonucleotides” reciting in step (a) “each site for electronically carrying out a part of a synthesis of oligonucleotides”; and claim 35 is directed to a “method of fabricating a plurality of individual chips for conducting a synthesis of oligonucleotides to form oligonucleotide arrays” reciting in step (a) “each site for electronically carrying out a synthesis of an

oligonucleotide to form oligonucleotide arrays”. The methods of the claims, however, comprise just two steps – “(a) preparing a plurality of said chips on a single silicon substrate, wherein each of said chips has a matrix of electronically addressable sites”, and “(b) severing said single silicon substrate into said individual chips”. The limitations in the preamble (“for conducting ...”) and in step (a) (“for electronically carrying out ...”) mentioned above are intended use recitations that merely recite the purpose of the process or the intended use of the structure and thus have not been accorded any patentable weight.

See MPEP 2111.02: A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 481. Also, “[i]n a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.” *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). Thus, the recitations in each of the claims described above (in the preamble “for conducting ...” and in step (a) “for electronically carrying out ...”) have not been given any patentable weight.

Cozzette et al disclose a method for the “mass production of uniform wholly microfabricated biosensors” that are created by a “method for the

microfabrication of electronic devices” that allows for “close control over the dimensional features of the various components and layers established on a suitable substrate” (see Abstract). The production method of Cozzette et al solves the previous problem of not being able to make biosensor electronic devices in a mass production mode (i.e. necessity of dicing the wafers before establishment of bilayers); see Section 2.2 of the patent, which describes the prior art, specifically, column 4, lines 7-20. Cozzette et al specifically describe “wafer level manufacturing procedures” (column 15, beginning on line 14). The reference discloses making a plurality of sensors (reading on the claimed “chips”) on a silicon substrate (see, for example, Section 5.1, especially column 21, lines 54-58). The different areas and layers of the sensor read on the claimed “matrix of electronically addressable sites” see, for example, Figure 1 of the patent). Cozzette et al discloses “dicing the wafer to yield individual glucose sensors” (see Section 5.1.5, beginning in column 40, line 56), which reads on the instant step (b) in claim 33. Thus, Cozzette et al reads directly on the instantly claimed steps of “(a) preparing a plurality of said chips on a single silicon substrate, wherein each of said chips has a matrix of electronically addressable sites”, and “(b) severing said single silicon substrate into said individual chips”. There does not appear to be a manipulative difference between the instant claims and the prior art.

Lastly, it is noted that an embodiment of the sensors of Cozzette et al uses “oligonucleotides, polynucleotides, molecules of DNA, molecules of RNA, active

fragments or subunits or single strands...” as the ligand receptor in the sensor; see patented claims 41 and 43 of Cozzette. Thus, clearly the prior art structure is capable of performing the intended use and meets the limitations of the claims (see *In re Casey* and *In re Otto*, cited above).

Response to Arguments

7. Applicant’s arguments filed December 31, 2002 have been fully considered but are not found persuasive. The examiner’s rationale is set forth below.

8. Applicant’s arguments are directed at the differences between the intended use of the instant “chips” (i.e. “for conducting chemical reactions”, especially of oligonucleotides) and Cozette’s sensors. As stated in the rejection, the intended use recitations are not given patentable weight.

9. Also as stated in the rejection, “[i]n a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.” *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). A manipulative difference as compared to Cozette has not been demonstrated.

10. With respect to the amendment to step (a): the different areas and layers of the sensors of Cozette read on the claimed “matrix of electronically addressable sites” see,

for example, Figure 1 of the patent. Also, as an embodiment of the sensors of Cozzette et al uses "oligonucleotides, polynucleotides, molecules of DNA, molecules of RNA, active fragments or subunits or single strands...", the prior art structure is capable of performing the intended use and meets the limitations of the claims (see *In re Casey*, and *In re Otto*, cited above).

Status of Claims/Conclusion


11. No claims are allowed

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER